CONFIDENTIAL

TIRC Grant #33

Progress Report #1

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"Investigation of the Effects of Tobacco on the Human Vascular System in Living Volunteers; and in Particular of the Possibility that Certain Tobacco Effects are Based on Peculiar Allergic Susceptibility of Specific Individuals Rather than upon Obligatorily Toxic Products in Tobacco Smoke"

This is a report of the first 500 volunteers tested with tobacco extracts at the Judson Health Center in New York City. The individuals were mainly adults in the lower income group.

The volunteers were skin tested by the intracutaneous method with 1/20cc of five different types of tobacco extracts. The site of testing was observed for at least 20 minutes to note result of test. Only the marked reactions were considered positive for this study. Permanent tracings were obtained on all marked positive reactions and normal saline was used as a control.

Before skin testing the individual, a thorough personal and familial history of allergy was obtained in conjunction with specific questioning about peripheral vascular symptoms and pertinent smoking habits.

The tobacco extracts were prepared by Miss Margaret Ballard Strauss, Director of the Allergy Laboratory at University Hospital. The usual methods of extraction were used*. The following tobacco extracts were used for testing in 1000 unit phosphotungstic acid precipitable Nitrogen.

1. Burley
2. Virginia
3. Turkish
4. Mixed
5. Mixed (defatted)

The mixed tobacco extracts consisted of a mixture of equal amounts of popular brands of cigarettes - (Lucky Strike, Old Gold, Chesterfield, Camels, Pall Mall, Philip Morris).

One of the mixtures was made in the usual way by defatting with an organic solvent for the removal of fats and various organic components generally soluble in toluene or other similar fat solvents. After the tobacco was thus treated, it was then extracted with an aqueous extracting fluid. The non-defatted mixture was extracted with aqueous solution without previous treatment with organic solvent.

Dr. Walter Reddish and his staff at the Goldwater Memorial Hospital have studied volunteers that were skin tested in order to uncover any possible relationship between the skin test reactions and peripheral vascular disease. He has undertaken the following procedures:

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Source: https://www.industrydocuments.ucsf.edu/docs/kfvm0030

1. Ballistocardiograms
2. Electrocardiograms
3. Peripheral blood flow studies
4. Peripheral temperature changes

Recordings have been made before and after smoking special cigarettes composed of a mixture of the same brands used in making the tobacco extracts.

Unfortunately, these results have not been completely assembled and are not reportable at this time.

Respectfully submitted,

s/ Vincent J. Fontana, M.D.
for Marion B. Sulzberger, M.D.

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Source: https://www.industrydocuments.ucsf.edu/docs/kfvn0003

RESULTS

TABLE I

Individuals with positive skin tests* 79 (15.8%)

Individuals with negative skin tests 421 (84.2%)

* Marked positive skin reactions to one or more tobacco extracts.

TABLE II

Which particular tobacco extracts gave the most, and the least, number of positive reactions?

POSITIVE REACTIONS TO THE SPECIFIC TOBACCO EXTRACT

Burley	40 (50%)
Turkish	37 (46.8%)
Virginia	45 (57%)
Mixed	47 (59%)
Mixed (defatted)	30 (39%)

TABLE III

Do people with positive skin tests to tobacco have a tendancy to more peripheral vascular symptoms?

	total	vascular symptoms
POSITIVE skin test individuals	79	18 (22%)
NEGATIVE skin test individuals	421	47 (11%)

TABLE IV

Do people who react positive by skin tests to tobacco have more tobacco symptoms than those that have negative skin tests?

	total	tobacco symptoms
POSITIVE skin test individuals	79	14 (16%)
NEGATIVE skin test individuals	421	17 (4%)

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Source: https://www.industrydocuments.ucsf.edu/docs/kfmh0000

TABLE V

Do people with familial and personal history of allergy give more positive skin reactions to tobacco:

	total	personal allergy	familial allergy
POSITIVE skin test individuals	79	25 (31%)	19 (22%)
NEGATIVE skin test individuals	421	54 (12.8%)	57 (13.5%)

TABLE VI

Do smokers with positive skin tests have more tobacco symptoms than smokers with negative skin tests?

Smokers	total	tobacco symptoms
POSITIVE skin tests	52	14 (26%)
NEGATIVE skin tests	259	17 (6.5%)

TABLE VII

Do smokers who have positive skin tests have more vascular symptoms than smokers with negative skin tests?

Smokers	total	Vascular symptoms
Positive skin tests*	52	16 (30.7%)
Negative skin tests**	259	32 (12%)

TABLE VIII

Do non-smokers who have positive skin tests to tobacco have more vascular symptoms than non-smokers with negative skin tests?

Non-smokers	total	Vascular symptoms
Positive skin test*	27	2 (7.4%)
Negative skin test**	162	15 (9.2%)

* Individuals with positive skin tests.
** Individuals with negative skin tests.

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Source: https://www.industrydocuments.ucsf.edu/docs/knvf0000

CRITERIA USED IN TOBACCO STUDY

SKIN TESTS: Only the marked positive skin tests (with pseudopods) were considered in the final count of positive reactions.

VASCULAR SYMPTOMS: Patient was considered to have positive vascular symptoms if three or more of the following signs and symptoms were present.

1. Fainting spells
2. Tingling of the extremities
3. Cold extremities
4. Numbness
5. Muscular aches and pains

TOBACCO SYMPTOMS: Patient was considered to have symptoms related to tobacco if two or more of the following reactions were experienced when smoking.

1. Coughing
2. Sweating
3. Sneezing
4. Headaches
5. Dizziness
6. Cold, numbness and tingling of the extremities

PERSONAL ALLERGY: Positive if the patient has experienced any of the following.

Hay fever	Drug sensitivity
Asthma	Atopic dermatitis
Food Allergy	

FAMILIAL HISTORY: Positive if any member of the patient's immediate family had the following.

Hay fever	Drug sensitivity
Asthma	Atopic dermatitis
Food allergy	

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IMPRESSIONS

1. 15.8% of the 500 individuals tested showed positive skin tests to one or more of the tobacco extracts. (This figure is in general agreement with those published for the incidence of allergy in the general population.)

2. There were more reactions to the mixed brands of tobacco extract non-defatted, and fewer reactions to the defatted mixed extract. The defatting process would remove an appreciable quantity of esters, aldehydes, and other organic compounds - ordinarily thought to be volatilized in the smoke of the cigarette. This would tend to indicate that a large number of individuals reacted to this volatile aromatic fraction alone.

Source: https://www.industrydocuments.ucsf.edu/docs/kfvm0000

3. It would appear that vascular symptoms were reported twice as often in volunteers with positive skin tests than in those with negative skin tests.

4. Four times more individuals complained of tobacco symptoms if the skin tests were positive than if the skin tests were negative.

5. Individuals with positive skin tests to tobacco related twice as much evidence of personal and familial allergy than the negative skin test individuals.

6. Smokers with positive skin tests to tobacco are more likely to develop (4X more) tobacco symptoms than those with negative skin tests.

7. Smokers with positive skin tests had 2 1/2 times more vascular symptoms than smokers with negative skin tests.

8. In non-smokers the incidence of vascular symptoms was about the same whether the skin test was positive or negative.

s/ V. J. Fontana, M.D.

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Source: https://www.industrydocuments.ucsf.edu/docs/kfvn0000